



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application No. 10/717,378

Applicant: RAHMAN et al.

Filed: November 19, 2003

TC/AU: 1654

Examiner: RUSSEL, Jeffrey E.

Docket No.: 224491

Customer No.: 23460

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, the references listed on the enclosed Form PTO-1449 and/or Substitute Form PTO-1449 ("Form 1449") are submitted for consideration by the Examiner in the examination of the above-identified patent application.

The full consideration of the references in their entirety by the Examiner is respectfully requested and encouraged. Also, it is respectfully requested that the references be entered into the record of the present application and that the Examiner place his or her initials in the appropriate area on the enclosed Form 1449, thereby indicating the Examiner's consideration of each of the references.

The submission of the references listed on the Form 1449 is for the purpose of providing a complete record and is not a concession that any reference listed thereon is prior art to the invention claimed in the patent application. The right is expressly reserved to establish an invention date earlier than the above-identified filing date in order to remove any reference submitted herewith as prior art should it be deemed appropriate to do so.

MAILING/TRANSMISSION CERTIFICATE UNDER 37 CFR 1.8 OR 1.10			
I hereby certify that this document and all accompanying documents are, on the date indicated below, being <input checked="" type="checkbox"/> deposited with the U.S. Postal Service using "Express Mail" service in an envelope addressed in the same manner indicated on this document with Express Mail Label Number EL841130041US, <input type="checkbox"/> deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed in the same manner indicated on this document, or <input type="checkbox"/> facsimile transmitted to the U.S. Patent and Trademark Office at fax number: (571) 273-8300.			
Name (Print/Type)	Peter J. Phillips		
Signature	Peter J. Phillips 2/24/06	Date	February 24, 2006

Further, the submission of the references is not to be taken as a concession that they represent art that is relevant or analogous to the claimed invention. Accordingly, the right to argue that the references are not properly within the scope of prior art relevant to an examination of the claims in the above-identified application is also expressly reserved.

The Information Disclosure Statement is being filed:

☒ **within** any one of the following time periods: (a) within three months of the filing date of a national application other than a continued prosecution application under 37 CFR 1.53(d); (b) within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 of an international application; (c) before the mailing date of a first Office Action on the merits; or (d) before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

☐ **after** (a), (b), (c) or (d) above, but before the mailing date of a final action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and includes *one* of:

☐ the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below).

or

☐ the fee of \$180 set forth in 37 CFR 1.17(p) (see "Fees" below).

☐ **after** the mailing date of a final action under 37 CFR 1.113 or a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and on or before payment of the issue fee, and includes the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).

☐ **after** the mailing date of a Notice of Allowance under 37 CFR 1.311, and on or before payment of the issue fee, and **within** thirty days of receiving each item of information contained in the Information Disclosure Statement, and includes the Statement under 37 CFR 1.704(d) (see "Statement under 37 CFR 1.704(d)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).

NOTE: This is for original applications except applications for a design patent, filed on or after May 29, 2000, wherein a paper containing only an Information Disclosure Statement in compliance with 37 CFR 1.97 and 1.98 is being filed.

Copies of the References

☐ Copies of all of the references listed on the enclosed Form 1449 are enclosed herewith.

☒ Copies of U.S. patents and patent applications that are listed on the accompanying Form 1449 are not enclosed herewith. Copies of other references identified on the accompanying Form 1449 are enclosed herewith.

- ☐ Attached to each reference not in the English language is a concise explanation of the relevance pursuant to 37 CFR 1.98(a)(3). An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of the relevance pursuant to 37 CFR 1.98(a)(3).
- ☐ A copy of the foreign search report is enclosed herewith.
- ☐ The references listed on the enclosed Form 1449 were previously identified in the parent application(s) of the present application, and copies of the references were furnished at that time. Accordingly, additional copies of the references are not submitted herewith, so as not to burden the file with duplicate copies of references. The Examiner is respectfully requested to carefully review the references in accordance with the requirements set out in the Manual of Patent Examining Procedure. In accordance with 37 CFR 1.98(d), the details of the parent application(s) relied upon for an earlier filing date under 35 USC 120 in which copies of the references were previously furnished are set out below:

U.S. APPLICATIONS		STATUS (CHECK ONE)		
U.S. APPLICATIONS	U.S. FILING DATE	PATENTED	PENDING	ABANDONED
1.				
2.				
3.				

Statement under § 1.97(e)

- ☐ The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.
- ☐ The **undersigned** hereby states that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

Statement under § 1.704(d)

- ☐ The **undersigned** hereby states that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

Fees

- ☒ No fee is owed by the applicant(s).
☐ The **IDS Fee of \$180** under § 1.17(p) is enclosed herewith.

Method of Payment of Fees

- ☐ Attached is a check in the amount of \$180.00.
☐ Charge Deposit Account No. 12-1216 in the amount of \$180.00. (A duplicate copy of this communication is enclosed for that purpose.)

Authorization to Charge Additional Fees

- ☒ If any additional fees are owed in connection with this communication, please charge Deposit Account No. 12-1216. (A duplicate copy of this communication is enclosed for that purpose.)

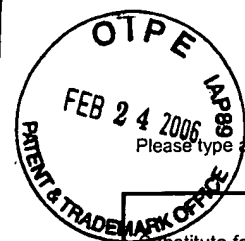
Instructions as to Overpayment


- ☒ Credit Account No. 12-1216.
☐ Refund.

Respectfully submitted,

M. Daniel Hefner, Registration No. 41,826
LEYDIG, VOIT & MAYER, LTD.
Two Prudential Plaza, Suite 4900
180 North Stetson
Chicago, Illinois 60601-6780
(312) 616-5600 (telephone)
(312) 616-5700 (facsimile)

Date: February 23, 2006



Please type a plus sign (+) inside this box → 

PTO/SB/08A/B (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)			Complete if Known		
			Application Number	10/717,378	
			Filing Date	November 19, 2003	
			First Named Inventor	RAHMAN, Aquilur	
			Group Art Unit	1654	
			Examiner Name	RUSSEL, Jeffrey E.	
Sheet	1	of	10	Attorney Docket Number	224491


U.S. PATENT DOCUMENTS						
Examiner Initials ¹	Cite No.	U.S. Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Filing Date if appropriate MM-DD-YYYY
		Document Number	Kind Code			
	IY	US- 5,003,097		03-26-1991	Beaucage et al.	
	IZ	US- 5,264,423		11-23-1993	Cohen et al.	
	JA	US- 5,276,019		01-04-1994	Cohen et al.	
	JB	US- 5,286,717		02-15-1994	Cohen et al.	
	JC	US- 5,965,519		10-12-1999	Yatvin et al.	
	JD	US- 6,126,965		10-03-2000	Kasid et al.	
	JE	US- 6,183,958		02-06-2001	Stanton, Jr.	
	JF	US- 6,291,175		09-18-2001	Sévigny et al.	
	JG	US- 6,333,314		12-25-2001	Kasid et al.	
	JH	US- 6,368,797		04-09-2002	Schappert	
	JI	US- 6,395,481		05-28-2002	Di Rienzo et al.	
	JJ	US- 6,475,736		11-05-2002	Stanton, Jr. et al.	
	JK	US- 6,559,129		05-06-2003	Kasid et al.	
	JL	US- 6,500,650		12-31-2002	Stanton, Jr. et al.	
	JM	US- 6,537,759		03-25-2003	Stanton, Jr. et al.	
	JN	US- 6,573,049		06-03-2003	Schappert	
	JO	US- 6,582,923		06-24-2003	Stanton, Jr. et al.	
	JP	US- 6,610,492		08-26-2003	Stanton, Jr. et al.	
	JQ	US- 6,664,062		12-16-2003	Stanton, Jr.	
	JR	US- 2002/0150943	A1	10-17-2002	Stanton, Jr. et al.	
	JS	US- 2003/0073123	A1	04-17-2003	Shen et al.	
	JT	US- 2003/0215489	A1	11-20-2003	Kasid et al.	
	JU	US- 2003/0219476	A1	11-27-2003	Ahmad et al.	
	JV	US- 2003/0225023	A1	12-04-2003	Kasid et al.	
	JW	US- 2003/0228317	A1	12-11-2003	Gokhale et al.	

* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

+ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

¹EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Please type a plus sign (+) inside this box → 

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>			Complete if Known		
			Application Number	10/717,378	
			Filing Date	November 19, 2003	
			First Named Inventor	RAHMAN, Aquilur	
			Group Art Unit	1654	
			Examiner Name	RUSSEL, Jeffrey E.	
Sheet	2	of	10	Attorney Docket Number	224491


U.S. PATENT DOCUMENTS						
Examiner Initials ¹	Cite No.	U.S. Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Filing Date, if appropriate MM-DD-YYYY
		Document Number	Kind Code			
	JX	US- 2003/0229040	A1	12-11-2003	Kasid et al.	
	JY	US- 2004/0005603	A1	01-08-2004	Kasid et al.	
	JZ	US- 2004/0082771	A1	04-29-2004	Kasid et al.	
	KA	US- 2004/0106571	A1	06-03-2004	Kasid et al.	
	KB	US- 2004/0115714	A1	06-17-2004	Kasid et al.	
	KC	US- 2004/0248218	A1	12-09-2004	Kasid et al.	
	KD	US- 2005/0002918	A1	01-06-2005	Strauss et al.	
	KE	US- 2005/0019387	A1	01-27-2005	Rahman et al.	
	KF	US- 2005/0148528	A1	07-07-2005	Gately	
	KG	US- 2005/0153297	A1	07-14-2005	Ahmad et al.	
	KH	US- 2005/0181037	A1	08-18-2005	Ahmad et al.	
	KI	US- 2005/0202074	A1	09-15-2005	Rahman	
	KJ	US- 2005/0238706	A1	10-27-2005	Ahmad et al.	
	KK	US- 2005/0249795	A1	11-10-2005	Zhang et al.	
	KL	US- 2005/0266068	A1	12-01-2005	Ahmad et al.	
	KM	US- 2005/0277611	A1	12-15-2005	Ahmad et al.	
	KN	US- 09/354,109			Kasid et al.	07-15-1999
	KO	US- 09/930,283			Kasid et al.	08-16-2001
	KP	US- 10/056,210			Kasid et al.	01-28-2002
	KQ	US- 10/239,598			Rahman	10-25-2000
	KR	US- 10/680,313			Kasid et al.	10-06-2003
	KS	US- 60/041,192			Kasid et al.	03-21-1997
	KT	US- 60/241,069			Rahman et al.	10-16-2000
	KU	US- 60/264,062			Kumar et al.	01-26-2001
	KV	US- 60/281,779			Kasid et al.	04-06-2001

* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

+ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

¹EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Please type a plus sign (+) inside this box → 

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>			Complete if Known		
			Application Number	10/717,378	
			Filing Date	November 19, 2003	
			First Named Inventor	RAHMAN, Aquilur	
			Group Art Unit	1654	
			Examiner Name	RUSSEL, Jeffrey E.	
Sheet	3	of	10	Attorney Docket Number	224491

U.S. PATENT DOCUMENTS						
Examiner Initials ¹	Cite No.	U.S. Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Filing Date, if appropriate MM-DD-YYYY
		Document Number	Kind Code			
	KW	US- 60/281,780			Kasid et al.	04-06-2001
	KX	US- 60/281,785			Kasid	04-06-2001
	KY	US- 60/281,796			Kasid et al.	04-06-2001
	KZ	US- 60/314,959			Rahman et al.	08-24-2001
	LA	US- 60/332,477			Strauss et al.	11-09-2001
	LB	US- 60/371,116			Kasid et al.	04-10-2002
	LC	US- 60/371,126			Kasid et al.	04-10-2002
	LD	US- 60/382,031			Gokhale et al.	05-22-2002
	LE	US- 60/382,411			Gately	05-20-2002
	LF	US- 60/383,340			Ahmad et al.	05-24-2002
	LG	US- 60/384,222			Ahmad et al.	05-29-2002
	LH	US- 60/405,378			Zhang et al.	08-23-2002
	LI	US- 60/419,277			Ahmad et al.	10-16-2002
	LJ	US- 60/429,285			Ahmad et al.	11-26-2002
	LK	US- 60/438,659			Ahmad et al.	01-07-2003
	LL	US- 60/444,958			Zhang et al.	02-03-2003
	LM	US- 60/446,895			Bhamidipati et al.	02-11-2003
	LN	US- 60/457,898			Gately et al.	03-26-2003
	LO	US- 60/467,331			Ahmad et al.	05-02-2003
	LP	US- 60/472,664			Jamil et al.	05-22-2003
	LQ	US- 60/480,669			Jamil et al.	06-23-2003
	LR	US- 60/495,260			Jamil et al.	08-13-2003
	LS	US- 60/514,658			Ahmad et al.	10-27-2003

* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

+ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

¹EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Please type a plus sign (+) inside this box → ☐

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/717,378
				Filing Date	November 19, 2003
				First Named Inventor	RAHMAN, Aquilur
				Group Art Unit	1654
				Examiner Name	RUSSEL, Jeffrey E.
Sheet	4	of	10	Attorney Docket Number	224491


FOREIGN PATENT DOCUMENTS								
Examiner Initials ¹	Cite No.	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	Check if Translation Provided**
		Office	Number	Kind Code				
	LT	EP	0 288 255	A2	10-26-1988	The Japanese Research and Development Association for Bioreactor System		<input type="checkbox"/>
	LU	EP	1 352 970	A1	10-15-2003	Nagoya Industrial Science Research Institute		<input type="checkbox"/>
	LV	SU	629927	A	10-30-1978	Bacterial Preparation Works		<input checked="" type="checkbox"/>
	LW	SU	1186212	A	10-23-1985	Inst. Biologicheskoy Med. Khimii		<input checked="" type="checkbox"/>
	LY	WO	98/43095	A	10-01-1998	Georgetown Univ.		<input type="checkbox"/>
	LY	WO	00/01366	A	01-13-2000	NeoPharm, Inc.		<input type="checkbox"/>
	MZ	WO	00/52210	A	09-08-2000	Variagenics, Inc.		<input type="checkbox"/>
	MA	WO	01/53460	A	07-26-2001	Variagenics, Inc.		<input type="checkbox"/>
	MB	WO	01/70220	A	09-27-2001	NeoPharm, Inc.		<input type="checkbox"/>
	MC	WO	02/32400	A	04-25-2002	NeoPharm, Inc.		<input type="checkbox"/>
	MD	WO	02/059337	A	08-01-2002	Georgetown Univ. School of Medicine		<input type="checkbox"/>
	ME	WO	02/081639	A	10-17-2002	Georgetown Univ.		<input type="checkbox"/>
	MF	WO	02/081640	A	10-17-2002	Georgetown Univ.		<input type="checkbox"/>
	MG	WO	02/081641	A	10-17-2002	Georgetown Univ.		<input type="checkbox"/>
	MH	WO	02/081642	A	10-17-2002	Georgetown Univ.		<input type="checkbox"/>
	MI	WO	02/088714	A	11-07-2002	McGill University		<input type="checkbox"/>
	MJ	WO	03/013536	A	02-20-2003	Epidauros Biotechnologie AG		<input type="checkbox"/>

* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

+ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

¹EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Please type a plus sign (+) inside this box → 

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>			Complete if Known		
			Application Number	10/717,378	
			Filing Date	November 19, 2003	
			First Named Inventor	RAHMAN, Aquilur	
			Group Art Unit	1654	
			Examiner Name	RUSSEL, Jeffrey E.	
Sheet	5	of	10	Attorney Docket Number	224491

FOREIGN PATENT DOCUMENTS								
Examiner Initials ¹	Cite No.	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	Check if Translation Provided**
		Office	Number	Kind Code				
	MK	WO	03/013537	A	02-20-2003	Epidauros Biotechnologie AG		<input type="checkbox"/>
	ML	WO	03/018018	A	03-06-2003	NeoPharm, Inc.		<input type="checkbox"/>
	MM	WO	03/039600	A	05-15-2003	NeoPharm, Inc.		<input type="checkbox"/>
	MN	WO	03/070221	A	08-28-2003	Georgetown Univ.		<input type="checkbox"/>
	MO	WO	03/099213	A	12-04-2003	NeoPharm, Inc.		<input type="checkbox"/>
	MP	WO	03/099830	A	12-04-2003	NeoPharm, Inc.		<input type="checkbox"/>
	MQ	WO	03/102011	A	12-11-2003	NeoPharm, Inc.		<input type="checkbox"/>
	MR	WO	2004/017944	A	03-04-2004	NeoPharm, Inc.		<input type="checkbox"/>
	MS	WO	2004/035523	A	04-29-2004	NeoPharm, Inc.		<input type="checkbox"/>
	MT	WO	2004/039817	A	05-13-2004	NeoPharm, Inc.		<input type="checkbox"/>
	MU	WO	2004/062569	A	07-29-2004	NeoPharm, Inc.		<input type="checkbox"/>
	MV	WO	2004/069224	A	08-19-2004	NeoPharm, Inc.		<input type="checkbox"/>
	MW	WO	2004/071466	A	08-26-2004	NeoPharm, Inc.		<input type="checkbox"/>
	MX	WO	2004/087758	A	10-14-2004	NeoPharm, Inc.		<input type="checkbox"/>
	MY	WO	2005/000266	A	01-06-2005	NeoPharm, Inc.		<input type="checkbox"/>
	MZ	WO	2005/000318	A	01-06-2005	NeoPharm, Inc.		<input type="checkbox"/>
	NA	WO	2005/042028	A	05-12-2005	NeoPharm, Inc.		<input type="checkbox"/>
	NB	WO	2005/067632	A	07-28-2005	NeoPharm, Inc.		<input type="checkbox"/>


OTHER - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials ¹	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Check if Translation Provided**
	NC	Office Action mailed December 30, 2005, in U.S. Patent Application No. 10/424,258.	<input type="checkbox"/>
	ND	ANDO et al., "UGT1A1 genotypes and glucuronidation of SN-38, the active metabolite of irinotecan," <i>Ann. Oncol.</i> , 9, 845-847 (1998).	<input type="checkbox"/>

* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

+ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

¹EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Please type a plus sign (+) inside this box → 

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)			Complete if Known		
			Application Number	10/717,378	
			Filing Date	November 19, 2003	
			First Named Inventor	RAHMAN, Aquilur	
			Group Art Unit	1654	
			Examiner Name	RUSSEL, Jeffrey E.	
Sheet	6	of	10	Attorney Docket Number	224491


OTHER - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials ¹	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Check if Translation Provided**
	NE	ANDO et al., "Polymorphisms of UDP-glucuronosyltransferase gene and irinotecan toxicity: a pharmacogenetic analysis," <i>Cancer Res.</i> 60, 6921-6926 (2000).	<input type="checkbox"/>
	NF	BOSMA et al., "Bilirubin UDP-glucuronosyltransferase 1 is the only relevant bilirubin glucuronidating isoform in man," <i>J. Biol. Chem.</i> 269, 17960-17964 (1994).	<input type="checkbox"/>
	NG	BOSMA et al., "The genetic basis of the reduced expression of bilirubin UDP-glucuronosyltransferase 1 in Gilbert's syndrome," <i>New Engl. J. Med.</i> 333, 1171-1175 (1995).	<input type="checkbox"/>
	NH	CERSOSIMO et al., "A new antineoplastic agent for the management of colorectal cancer," <i>Ann. Pharmacother.</i> 32:1324-1333, (1998)	<input type="checkbox"/>
	NI	DRUMMOND et al., "Optimizing Liposomes for Delivery of Chemotherapeutic Agents to Solid Tumors," <i>Pharmacol. Rev.</i> 51, 691-743 (1999).	<input type="checkbox"/>
	NJ	FISHMAN et al., "Phase I study of Liposomal SN-38 (LE-SN38) in Patients With Advanced Cancer: Pharmacogenomics and Pharmacokinetics," <i>AARC-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics</i> (Boston, MA), Abstract B250 (November 2003).	<input type="checkbox"/>
	NK	FISHMAN et al., "Phase I study of liposome encapsulated mitoxantrone (LEM) in patients with advanced cancers," <i>Ann. Oncol.</i> 13 (Suppl. 5), 23 (2002).	<input type="checkbox"/>
	NL	GILBERT et al., "Phase I study of 9-nitrocamptothecin (9-NC) liposome aerosol for the treatment of primary and metastatic cancer to the lungs: effect of dose escalation on bronchoalveolar lavage (BAL) and plasma drug levels," <i>Proc. Am. Assoc. Cancer Res.</i> , 43, 430 (Abstract 2138) (2002).	<input type="checkbox"/>
	NM	GUPTA et al., "Metabolic fate of irinotecan in humans: correlation of glucuronidation with diarrhea," <i>Cancer Res.</i> 54, 3723-3725 (1994).	<input type="checkbox"/>
	NN	GUTBERLET et al., "Cardiolipin, α -D-glucopyranosyl, and L-lysylcardiolipin from Gram-positive bacteria: FAB MS, monifilm and X-ray powder diffraction studies," <i>Biochim. Biophys. Acta</i> , 463, 307-322 (2000).	<input type="checkbox"/>
	NO	HECHT, "Gastrointestinal toxicity of irinotecan," <i>Oncology</i> 12, 72-78 (1998).	<input type="checkbox"/>

* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a).(3).

+ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a).(3).

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

¹EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Please type a plus sign (+) inside this box → 

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)			Complete if Known		
			Application Number	10/717,378	
			Filing Date	November 19, 2003	
			First Named Inventor	RAHMAN, Aquilur	
			Group Art Unit	1654	
			Examiner Name	RUSSEL, Jeffrey E.	
Sheet	7	of	10	Attorney Docket Number	224491


OTHER - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials ¹	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Check if Translation Provided**
	NP	HSIANG et al., "Arrest of replication forks by drug-stabilized topoisomerase I-DNA cleavable complexes as a mechanism of cell killing by camptothecin," <i>Cancer Res.</i> 49, 5077-5082 (1989).	<input type="checkbox"/>
	NQ	HSIANG et al., "Camptothecin induces protein-linked DNA breaks via mammalian DNA topoisomerase I," <i>J. Biol. Chem.</i> 260, 14873-14878 (1985).	<input type="checkbox"/>
	NR	INNOCENTI et al., "UGT1A1 *28 polymorphism is a predictor of neutropenia in irinotecan chemotherapy," <i>Proc. Am. Soc. Clin. Oncol.</i> , 22, 124 (Abstract 495) (2003).	<input type="checkbox"/>
	NS	IYER et al., "Genetic predisposition to the metabolism of irinotecan (CPT-11). Role of uridine diphosphate glucuronosyltransferase isoform 1A1 in the glucuronidation of its active metabolite (SN-38) in human liver microsomes," <i>J Clin Invest</i> 101:847-854, (1998)	<input type="checkbox"/>
	NT	IYER et al. "Phenotype-genotype correlation of in vitro SN-38 (active metabolite of irinotecan) and bilirubin glucuronidation in human liver tissue with UGT1 A1 promoter polymorphism," <i>Clin. Pharmacol. Ther.</i> , 65, 576-582 (1999).	<input type="checkbox"/>
	NU	IYER et al., "UGT1A1 *28 polymorphism as a determinant of irinotecan disposition and toxicity," <i>Pharmacogenetics</i> , 2, 43-47 (2002).	<input type="checkbox"/>
	NV	KEHRER et al., "Factors involved in prolongation of the terminal disposition phase of SN-38: clinical and experimental studies," <i>Clin. Cancer Res.</i> , 6, 3451-3458 (2000).	<input type="checkbox"/>
	NW	KNIGHT et al., "Anticancer effect of 9-nitrocamptothecin liposome aerosol on human cancer xenografts in nude mice," <i>Cancer Chemother. Pharmacol.</i> , 44, 177-186 (1999).	<input type="checkbox"/>
	NX	KRAUT et al., "Pharmacogenomic and pharmacokinetic assessment of liposome encapsulated SN-38 (LE-SN38) in advanced cancer patients," presented at ASCO (American Society of Clinical Oncology), New Orleans, LA, June 5-8, 2004, Abstract 2501 (June 5, 2004).	<input type="checkbox"/>

* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a).(3).

+ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a).(3).

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

¹EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Please type a plus sign (+) inside this box → 

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)			Complete if Known		
			Application Number	10/717,378	
			Filing Date	November 19, 2003	
			First Named Inventor	RAHMAN, Aquilur	
			Group Art Unit	1654	
			Examiner Name	RUSSEL, Jeffrey E.	
Sheet	8	of	10	Attorney Docket Number	224491


OTHER - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials ¹	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Check if Translation Provided**
	NY	KUNIMOTO et al., "Antitumor activity of 7-ethyl-10-[4-(1-piperidino)-1-piperidino]carbonyloxy-camptothecin, a novel water soluble derivative of camptothecin, against murine tumors," <i>Cancer Res.</i> 47:5944-5947, (1987)	<input type="checkbox"/>
	NZ	LAMPE et al., "UDP-glucuronosyltransferase (UGT1A1 *28 and UGT1A6*2) polymorphisms in Caucasians and Asians: relationships to serum bilirubin concentrations," <i>Pharmacogenetics</i> , 9, 341-349 (1999).	<input type="checkbox"/>
	OA	LAVELLE et al. "Preclinical evaluation of CPT-1 1 and its active metabolite SN-38," <i>Semin. Oncol.</i> , 23, 11-20 (1996).	<input type="checkbox"/>
	OB	MATHIJSEN et al., "Impact of body-size measures on irinotecan clearance: alternative dosing recommendations," <i>J. Clin. Oncol.</i> , 20, 81-87 (2002).	<input type="checkbox"/>
	OC	MONAGHAN et al., "Genetic variation in bilirubin UDP-glucuronosyltransferase gene promoter and Gilbert's syndrome," <i>Lancet</i> , 347, 578-581 (1996).	<input type="checkbox"/>
	OD	O'LEARY et al, "Camptothecins: a review of their development and schedules of administration," <i>Eur. J. Cancer.</i> , 34, 1500-1508 (1998).	
	OE	OSBORNE, "Nastech licenses RNAi patents to boost tight junctions work," <i>BioWorld Today</i> , 15 (21), 1, 6 (February 3, 2004).	<input type="checkbox"/>
	OF	PFIZER, INC., Package insert for Camptosar® (July 2005).	<input type="checkbox"/>
	OG	PITOT et al, "Phase I dose-finding and pharmacokinetic trial of irinotecan hydrochloride (CPT-11) using a once-every-three-week dosing schedule for patients with advanced solid tumor malignancy," <i>Clin Cancer Res.</i> , 6, 2236-2244 (2000).	<input type="checkbox"/>
	OH	RAINIER et al., "Phase transition characteristics of diposphatidyl-glycerol (cardiolipin) and stereoisomeric phosphatidylglycerol bilayers: mono- and divalent metal ion effects," <i>Biochim. Biophys. Acta</i> , 558, 187-198 (1979).	<input type="checkbox"/>
	OI	RIVORY et al, "Kinetics of the in vivo interconversion of the carboxylate and lactone forms of irinotecan (CPT-11) and of its metabolite SN-38 in patients," <i>Cancer Res.</i> 54:6330-6333, (1994)	<input type="checkbox"/>

* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a).(3).

+ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a).(3).

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

¹EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Please type a plus sign (+) inside this box → 

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)			Complete if Known		
			Application Number	10/717,378	
			Filing Date	November 19, 2003	
			First Named Inventor	RAHMAN, Aquilur	
			Group Art Unit	1654	
			Examiner Name	RUSSEL, Jeffrey E.	
Sheet	9	of	10	Attorney Docket Number	224491


OTHER - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials ¹	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Check if Translation Provided**
	OJ	RIVORY et al, "Pharmacokinetic interrelationships of irinotecan (CPT-11) and its-three major plasma metabolites in patients enrolled in phase I/II trials," <i>Clin. Cancer Res.</i> , 3, 1261-1266 (1997).	<input type="checkbox"/>
	OK	RIVORY, "Metabolism of CPT-11 impact on activity," <i>Ann. N. Y. Acad. Sci.</i> , 922, 205-215 (2000).	<input type="checkbox"/>
	OL	ROTHENBERG, "Topoisomerase I inhibitors: review and update," <i>Ann. Oncol.</i> 8:837-855, (1997)	
	OM	SANGHANI et al., "Carboxylesterases expressed in human colon tumor tissue and their role in CPT-11 hydrolysis," <i>Clin. Cancer Res.</i> , 9 (13), 4983-4991 (October 15, 2003).	<input type="checkbox"/>
	ON	SASAKI et al., "Pharmacological correlation between total drug concentration and lactones of CPT-11 and SN-38 in patients treated with CPT-11," <i>Cancer Res.</i> , 86, 111-116 (1995).	<input type="checkbox"/>
	OO	SCHAEPPPI et al., "Toxicity of camptothecin (NSC-100880)," <i>Cancer Chemother. Rep.</i> , 5, 25-36 (1974).	<input type="checkbox"/>
	OP	SLATTER et al., "Pharmacokinetics, metabolism and excretion of irinotecan (CPT-11) following iv infusion of [14C]CPT-11 in cancer patients," <i>Drug Metab. Dispos.</i> , 28, 423-433 (2000).	<input type="checkbox"/>
	OQ	STRASSBURG et al., "Jaundice, genes and promoters," <i>J. Hepatol.</i> , 33, 467-479 (2000).	<input type="checkbox"/>
	OR	TAKIMOTO et al., "The captothecins," in <i>The camptothecins. Cancer chemotherapy and biotherapy</i> , 2nd ed. (Chabner et al., eds.), Chapter 19, 463-484 (Lippincott-Raven, Philadelphia, PA, 1996).	<input type="checkbox"/>
	OS	TREAT et al., "Phase I trial in advanced malignancies with liposome encapsulated paclitaxel (LEP)," <i>Clin. Cancer Res.</i> , 6, 4492s (2000).	<input type="checkbox"/>
	OT	VANHOEFER et al., "Irinotecan in the treatment of colorectal cancer: clinical overview," <i>J. Clin. Oncol.</i> , 19, 1501-1518 (2001).	<input type="checkbox"/>

* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a).(3).

+ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a).(3).

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

¹EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Please type a plus sign (+) inside this box → 

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/717,378
				Filing Date	November 19, 2003
				First Named Inventor	RAHMAN, Aquilur
				Group Art Unit	1654
				Examiner Name	RUSSEL, Jeffrey E.
Sheet	10	of	10	Attorney Docket Number	224491

OTHER - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials ¹	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Check if Translation Provided**
	OU	VAUGHN et al., "A phase I study of a new liposome encapsulated doxorubicin (LED) formulation in advanced malignancies," <i>Proc. Am. Soc. Clin. Oncol.</i> , 19 (23), 1a (Abstract 892) (1999).	<input type="checkbox"/>
	OV	WADLER et al., "Recommended guidelines for the treatment of chemotherapy-induced diarrhea," <i>J. Clin. Oncol.</i> , 16, 3169-3178 (1998).	<input type="checkbox"/>
	OW	WASSERMAN et al., "Severe CPT-11 toxicity in patients with Gilbert's syndrome: two case reports," <i>Ann. Oncol.</i> , 8, 1049-1051 (1997).	<input type="checkbox"/>

* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a).(3).

+ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a).(3).

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

¹EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.